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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/684,178

10/10/2003

Gerardo M. Castillo

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PROTEOTECH, INC.
12040 115TH AVE NE
KIRKLAND, WA 98034-6931

EXAMINER

COVINGTON, RAYMOND K

ART UNIT

PAPER NUMBER

1625

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DELIVERY MODE

07/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/684,178	Applicant(s) CASTILLO ET AL.	
	Examiner Raymond Covington	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22,27,39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22,27,39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22, 27, 39 and 40 are again rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/12102 or WO 98/52302.

Castillo et al WO 00/12102 is applied as in the previous office action. in response to Applicant's traversal dated 1-19-2007. Applicant argued that Castillo et al. does not disclose that the plant *Uncaria tomentosa* contains procyanidin B2 nor does Castillo et al. disclose treating a mammal with procyanidin B2 in an amount ranging from 0.1 mg/kg of body weight per day and 1000 mg/kg of body weight per day. This rejection should have been maintained. The instant claims do not preclude the administration of "plant matter". The instant claims merely require the administration of procyanidin B2 in a concentration of 0.1 mg/kg of body weight per day and 1000 mg/kg of body weight per day. Given that 1) *Uncaria tomentosa* bark powder contains 0.05% (by weight) procyanidin B2 (see page 45 of the instant specification and Applicant's arguments); 2) that Castillo et al.

disclose the administration of compositions comprising *Uncaria tomentosa* bark powder in an 8:1 ratio to other components (see page 5 of Castillo et al.); and 3) that Castillo et al. disclose the administration of their "blended" compositions in a dosage of "10 to 1000 mg/kg of body weight of the patient" (see page 4), Castillo et al. discloses the effective administration of 0.44 mg/kg of body weight of the patient which meets the dosage limitation of the instant claims. Furthermore, Castillo et al. disclose that the extract alone has efficacy (see page 3).

WO 98/51302 (on IDS) is applied as art as well since it was explicitly disclosed in WO 00/12102 that *Uncaria tomentosa* bark powder extracts had efficacy as an inhibitor of amyloid formation in Alzheimer's disease and the disrupting and/or dissolving of amyloid depositis and other accumulations (see page 3 of WO 00/12102).

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 22, 27, 39 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Snow et al US 2003/0017998 (listed on IDS).

Snow et al discloses the use of procyanidin B2 for the treatment of amyloid diseases (see paragraphs [0016], [0027] and [0030]). Reference also disclose the dosage as being between 10 to 1,000 mg/kg body weight (see paragraph [032]). IV. WO 02/76381 (on IDS) should have been applied as art under 35 U.S.C. 102(e) as it discloses the use of procyanidin B2 for the treatment of amyloid diseases (see page 4-5 and 10. It should be noted that Compound H2 is in fact procyanidin B2). Reference also disclose the dosage as being between 10 to 1,000 mg/kg body weight (see page 10-11).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22, 27, 39 and 40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-10 and 12-19 of U.S. Patent No. 6,607,758. Although the conflicting claims are not identical, they are not patentably distinct from each other because The administration of the recited plant composition would necessarily result in the administration of the claimed dosage of procyanidin B2.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (571) 272-0681. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres at telephone number (571) 272-0867.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair->

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direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/R. C./
Examiner, Art Unit 1625
RKC

/Janet L. Andres/
Supervisory Patent Examiner,
Art Unit 1625